

14. (Once amended) A method for delivering an aerosolized active agent to the lungs of a human patient, said method comprising delivering the aerosolized active agent formulation at a high flow resistance of at least 0.4 (cmH<sub>2</sub>O)<sup>1/2</sup>/SLM [for an initial time period] and subsequently providing a lower flow resistance.

15. (Once amended) The method of claim [13] 14 wherein the high flow resistance is a resistance of between 0.4 and 2 (cmH<sub>2</sub>O)<sup>1/2</sup>/SLM.

16. (Once amended) The method of claim [13] 14 wherein the lower flow resistance is a resistance of between 0 and 0.3 (cmH<sub>2</sub>O)<sup>1/2</sup>/SLM

17. (Once amended) The method of claim [13] 14 wherein the high flow resistance corresponds to a flow rate of 15 liters per minute or less.

18. (Once amended) The method of claim [13] 14 wherein the lower flow resistance corresponds to a flow rate of 15-80 liters per minute.

19. (Once amended) The method of claim [13] 14 wherein the high flow resistance is provided for an [the] initial time period [is a period ]of less than 10 seconds.

20. (Once amended) The method of claim [19] 14 wherein the high flow resistance is provided for an [the] initial time period [is a period ]of less than 5 seconds.

#### REMARKS

Claims 1,2, and 4-20 are pending in the above identified application. Claims 1 and 14 have been amended and claim 3 has been cancelled. Applicants respectfully submit that the claims are supported throughout the specification as filed and no new matter is presented by these amendments. Entry of the amendments is respectfully requested.

Claim 1 has been rejected under 35 U.S.C. 102(b) as being anticipated by Laube et al. In response thereto, claim 1 has been amended to recite that the device comprises a flow resistance modulator that modulates the resistance of the flow of aerosolized active agent formulation to produce an initial target flow rate and a second target flow rate that is greater than the initial target flow rate. Laube et al. does not disclose modulating the flow of the aerosolized active agent formulation by the methods and device disclosed therein to provide a second target flow rate greater than the initial target flow rate as claimed. In view of the amendment to claim 1,

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Applicant respectfully submits that the rejection has been overcome and should be withdrawn.

Claims 1-20 have also been rejected under 35 U.S.C. 112, second paragraph, as being indefinite. In particular, the Examiner has objected to the phrases "initial target flow rate", "high flow resistance", "initial time period", and "in a manner that is...". Claims 1 and 14 have been amended in a manner which Applicant believes provides clarity to the claims and overcomes the objections raised by the Examiner. Specifically, the target flow rate has been specified in claim 1 as being less than 15 liters/min, the high flow resistance has been specified as greater than 0.4 (cmH<sub>2</sub>O)<sup>1/2</sup> / SLM and the phrase "initial time period" and "in a manner that is..." have been deleted. Additionally, the amendments recite all necessary steps defining how the process/method is actually practiced. In view of these amendments, Applicant respectfully submits that the rejections under 112, second paragraph, have been overcome and should be withdrawn.


#### CONCLUSION

Applicants believe that all the pending claims are presently in condition for allowance. However, the Examiner is invited to telephone the undersigned attorney at the number below if it is believed that this will expedite prosecution of the present application.

Respectfully submitted,

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